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How Federal and State Regulatory Systems Perpetuate Environmental Injustice in the United States: Industrial Ethylene Oxide Emissions as a Case Study

Adrian Wood and Marilyn Howarth

ABSTRACT

Background: Ethylene oxide (EtO), a known human carcinogen, is emitted from facilities across the United States. A 2018 assessment by the Environmental Protection Agency (EPA) showed that areas around EtO-emitting facilities had cancer risk levels up to 24 times the national average. The EPA notified the state Department of Environmental Protection (DEP) about the high cancer risk to their residents. Our aim was to analyze actions and implementation equity at the federal, state, and community levels since the EPA notification.

Methods: Using publicly available data, we identified U.S. emitters of EtO and then analyzed community, state, and federal actions since the EPA notification through content analysis of internet data using the lens of the environmental inequality formation (EIF) theory.

Results: Thirty-one of a total 654 EtO-emitting facilities have an estimated cancer risk of over 100 in a million in neighboring census tracts and are located in 13 states and Puerto Rico, representing 7 EPA regions. Content analysis identified themes of community outcry, agency involvement, and legislative action and found no action without community outcry. By January 2021, 2 facilities had closed, 5 facilities had cut emissions, and 24 facilities in 9 states and 5 EPA regions had taken no action.

Discussion: Wealthier white neighborhoods saw facilities close or cut emissions. Differences in state response correlated with differences in community pressure and state priority setting, resulting in over 1 million people having continued significant EtO exposure for years.

Conclusions: The impotence of the federal and state regulatory framework perpetuates environmental injustice in the United States.

Keywords: document analysis, hazardous air pollution, environmental racism

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INTRODUCTION

ENVIRONMENTAL INJUSTICE REFERS to the disproportionate exposure of low-income minority communities to environmental hazards, often due to unequal protection through laws, regulations, and enforcement.¹ This injustice has been documented since the 1980s with the demonstration that hazardous waste sites were disproportionately located in low-income minority communities.²

Recent studies document continued unequal impacts, not only in regard to hazardous waste sites but also in exposure to air pollution, a serious public health issue that leads to an estimated seven million deaths annually worldwide.^{3,4,5,6,7}

The federal Clean Air Act (CAA), established in 1970 and strengthened through subsequent amendments, was an important step to limit air pollution and protect health.⁸ Through the CAA, the Environmental Protection Agency (EPA) sets air quality standards for pollutants. Although the CAA is a federal law, in practice, the EPA has delegated the responsibility for its enforcement to the states.⁹

The current framework for environmental protection in the United States is based around a system of shared responsibility across levels of government.¹⁰ Most often, the federal government (i.e., the EPA) sets national standards, which are then implemented by the state

government (i.e., the state Department of Environmental Protection [DEP]). Variable enforcement can be seen in state decisions impacting monitoring, regulating, and controlling emissions.

In this study, we use ethylene oxide (EtO) as an example of how the EPA delegation of enforcement authority of the CAA to states can lead to unequal protection of communities against hazardous air pollution. EtO came to the attention of many communities after the EPA released their National Air Toxics Assessment (NATA) in August 2018. The NATA is updated periodically using emission data from point and nonpoint sources, mobile sources, fires, and biogenics, in addition to secondary information to estimate cancer risks from toxic air pollution across the United States.^{11,12}

This amalgamation of data provides the basis for a regional risk assessment of air toxics. The last NATA was released in August of 2018 based on data from 2014. While the updated assessment released showed that toxic air pollution as a whole had decreased since the last assessment based on data from 2011, estimated cancer risks in some communities had drastically increased, including areas in Louisiana, Illinois, Georgia, and Pennsylvania.

These increases in estimated cancer risk were due to EPA's recent reclassification of EtO as a confirmed human carcinogen. EtO is a gas primarily used as an intermediate in the manufacture of ethylene glycol, found in a range of consumer products, and as a sterilizing agent for medical equipment.¹³ EtO has been studied for its carcinogenic properties, which include DNA-damaging and mutagenic effects.¹⁴

Large cohort studies have found positive exposure-response trends for lymphohematopoietic cancer and breast cancer mortality in workers exposed to EtO in sterilization facilities.^{15,16} In 1994, the International

¹Robert D. Bullard (ed). *Unequal Protection: Environmental Justice and Communities of Color*. (Sierra Club Books, 1994).

²B.F. Chavis and C.T. Lee. *Toxic Wastes and Race in the United States: A National Report on the Racial and Socio-economic Characteristics of Communities with Hazardous Waste Sites*. (Commission for Racial Justice, United Church of Christ, 1987).

³M.L. Miranda, S.E. Edwards, M.H. Keating, and C.J. Paul. "Making the Environmental Justice Grade: The Relative Burden of Air Pollution Exposure in the United States." *International Journal of Environmental Research and Public Health* 8 (2011): 1755–1771.

⁴M.J. Bell and K. Ebisu. "Environmental Inequality in Exposures to Airborne Particulate Matter Components in the United States." *Environmental Health Perspectives* 120 (2012): 1699–1704.

⁵Christopher W. Tessum, David A. Paoletta, Sarah E. Chambliss, Joshua S. Apte, Jason D. Hill, and Julian D. Marshall. "PM2.5 Polluters Disproportionately and Systemically Affect People of Color in the United States." *Science Advances* 7 (2021): EABF4491.

⁶M. Pastor, R. Morello-Frosch, and J.L. Sadd. "The Air Is Always Cleaner on the Other Side: Race, Space, and Ambient Air Toxics Exposures in California." *Journal of Urban Affairs* 27 (2005): 127–148.

⁷World Health Organization. How air pollution is destroying our health. 2020. <<https://www.who.int/airpollution/news-and-events/how-air-pollution-is-destroying-our-health>>. (Last accessed on August 15, 2021).

⁸The Clean Air Act (CAA) (42 U.S.C. 7401 et seq.).

⁹U.S. Environmental Protection Agency. "Government Partnerships to Reduce Air Pollution." <<https://www.epa.gov/clean-air-act-overview/government-partnerships-reduce-air-pollution>>. (Last accessed on August 15, 2021).

¹⁰D. Konisky and N. Woods. "Environmental Federalism and the Trump Presidency: A Preliminary Assessment." *Publius: The Journal of Federalism* 48 (2018): 345–371.

¹¹U.S. Environmental Protection Agency. 2014 National Air Toxics Assessment. (National Center for Environmental Assessment Office of Research and Development U.S. Environmental Protection Agency, 2018). <<https://www.epa.gov/national-air-toxics-assessment/2014-national-air-toxics-assessment>>. (Last accessed on August 14, 2021).

¹²U.S. Environmental Protection Agency. 2011 National Air Toxics Assessment. (National Center for Environmental Assessment Office of Research and Development U.S. Environmental Protection Agency, 2015). <<https://www.epa.gov/national-air-toxics-assessment/2011-national-air-toxics-assessment>>. (Last accessed on August 14, 2021).

¹³Agency for Toxic Substances and Disease Registry. *Toxicological Profile for Ethylene Oxide*. (U.S. Department of Health and Human Services, Public Health Service, 1990).

¹⁴U.S. Environmental Protection Agency. *Evaluation of the Inhalation Carcinogenicity of Ethylene Oxide*. (National Center for Environmental Assessment Office of Research and Development U.S. Environmental Protection Agency, 2016).

¹⁵K. Steenland, L. Stayner, and J. Deddens. "Mortality Analyses in a Cohort of 18235 Ethylene Oxide Exposed Workers: Follow Up Extended from 1987 to 1998." *Occupational and Environmental Medicine* 61 (2004): 2–7.

¹⁶K. Steenland, E. Whelan, J. Deddens, L. Stayner, and E. Ward. "Ethylene Oxide and Breast Cancer Incidence in a Cohort Study of 7576 Women (United States)." *Cancer Causes and Control* 14 (2003): 531–539.

Agency for Research on Cancer (IARC) classified EtO as a Group 1 human carcinogen.¹⁷ The EPA did not classify EtO as a known carcinogen by inhalation until 2016, 22 years later. EPA's update in classification increased the risk value associated with EtO, which is used to calculate cancer risks, from 1 in 10,000 to 30 in 10,000 excess cancers per microgram per cubic meter of air.¹⁸

In 2018, when the NATA was released, communities around facilities that emit EtO saw an increase in estimated cancer risks. In census tracts with high EtO emissions, estimated cancer risks were found to be over 24 times the national average.¹⁹ Recent research in one of these communities showed that an EtO biomarker was found in persons living close to the facility at a significantly higher rate than persons living farther away, suggesting that surrounding communities were exposed to EtO emissions.²⁰

The release of the NATA in 2018 led to public outcry from some communities living in close proximity to these facilities. Some residents believed that the facilities must be in violation of EPA emission regulations. However, the facilities were emitting EtO at rates within their legally allowed limits established in 2006, 10 years before EtO was classified as a carcinogen by the EPA.²¹

The EPA acknowledged the risks of EtO in the assessment and sent out a notice to state agencies, offering to work with states to measure ethylene oxide in the outdoor air.²² To determine whether revisions to regulations were needed, the EPA noted that they would be "taking a closer look at air toxics regulations for industries that emit ethylene oxide."²³ The EPA also noted that they will seek additional information by conducting emission testing at facilities that emit EtO, focusing first on areas where the NATA estimates showed elevated cancer risk.²⁴

We aim to analyze actions related to EtO taken at the federal, state, and community levels using the environmental inequality formation (EIF) theory. EIF shifts the

focus from the outcomes of environmental injustice to the mechanisms behind these outcomes.²⁵ EIF does this by analyzing the importance of process and history, the role of multiple stakeholder relationships, social stratification, and a life cycle approach to the study of hazards.

This research uses this model to analyze involvement of multiple stakeholders in the decision-making process and shaping of environmental inequality around the regulation of EtO. Through this lens, we examine the effectiveness of the current regulatory framework in protecting the public from identified hazards, identify differences in state responses to EtO risk, and consider social and political factors that may be associated with any differences found.

METHODS

Study design

We used content analysis to analyze documents and websites to gather data on actions by state and federal agencies, communities, and legislators in reaction to the EPA NATA released in 2018.²⁶ We focused our search on documents and websites related to facilities that emit EtO at levels that were associated with elevated cancer risks of over 100 per million.

We used the NATA to identify facilities that emit EtO across the United States. We included all facilities where EtO emissions were associated with estimated cancer risk levels of over 100 per million, which is the threshold that the EPA has generally considered to be acceptable cancer risk in its rulemaking process.²⁷ We used geographic information system software to measure a 1-mile radius around each facility.

Data from the 2013 to 2017 American Community Survey were used to characterize the community located within this 1-mile radius of the facility. Data collected included median household income, population density, racial/ethnic makeup, and poverty level. We classified communities as environmental justice (EJ), using the EPA classification, as those with 20% or more individuals living in poverty and/or 30% or more of the population being a member of a minority group.²⁸

We searched through documents and websites related to EtO for the identified facilities. We searched for mentions of EtO on the EPA webpage and each state's DEP webpage. We also searched for press releases and quotes in local news articles that indicated the agency's

¹⁷IARC. "Some Industrial Chemicals." *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans* 60: (1994): 1–560.

¹⁸*Ibid.* Konisky and Woods (2018).

¹⁹*Ibid.* World Health Organization (2020).

²⁰E. Szwiec, L. Friedman, and S. Buchanan. "Levels of Ethylene Oxide Biomarker in an Exposed Residential Community." *International Journal of Environmental Research and Public Health* 17 (2020): 8646.

²¹U.S. Environmental Protection Agency. *Ethylene Oxide Emissions Standards for Sterilization Facilities: National Emission Standards for Hazardous Air Pollutants (NESHAP)*. (National Center for Environmental Assessment Office of Research and Development U.S. Environmental Protection Agency, 2006). <<https://www.epa.gov/stationary-sources-air-pollution/ethylene-oxide-emissions-standards-sterilization-facilities>>. (Last accessed on August 12, 2021).

²²U.S. Environmental Protection Agency. *Hazardous Air Pollutants: Ethylene Oxide: Agency Actions on Ethylene Oxide*. (U.S. Environmental Protection Agency, 2020). <<https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/agency-actions-ethylene-oxide#review>>. (Last accessed on August 10, 2021).

²³*Ibid.* Steenland *et al.* (2003).

²⁴*Ibid.*

²⁵D. Pellow. "Environmental Inequality Formation: Toward a Theory of Environmental Injustice." *American Behavioral Scientist* 43 (2000): 581–601.

²⁶G.A. Bowen. "Document Analysis as a Qualitative Research Method." *Qualitative Research Journal* 9 (2009): 27–40.

²⁷U.S. Environmental Protection Agency. *U.S. EPA's National Air Toxics Assessment (NATA) and Ethylene Oxide*. <https://www.epa.gov/sites/default/files/2019-08/documents/nata_overview_-_kelly_rimer.pdf>. (Last accessed on August 8, 2021).

²⁸Pennsylvania Department of Environmental Protection. *PA Environmental Justice Areas*. (Pennsylvania Department of Environmental Protection, 2020). <<https://www.dep.pa.gov/PublicParticipation/OfficeofEnvironmentalJustice/Pages/PA-Environmental-Justice-Areas.aspx>>. (Last accessed on August 10, 2021).

actions related to EtO. We used Google to search for community websites and local news articles with mentions of community activity around EtO emissions.

We also searched social media, including Facebook and Twitter, for mentions of EtO and the local facility. We searched industry websites for industry press releases. We applied the following terms to these searches: ["ethylene oxide," "EtO," name of each facility identified, and name of each city identified].

Last, we searched the relevant states' General Assembly legislation pages for any bills (introduced in 2018, 2019, or 2020) that included any mention of EtO. We searched for documents dated from August 2018 to December 2020. We applied the following search terms: ["ethylene oxide" and "EtO"].

Inclusion criteria for documents/webpages were as follows:

- must mention EtO,
- must be in relation to one of the 31 EtO facilities associated with elevated cancer risks of over 100 per million, and
- must be published after the release of the EPA NATA in August 2018.

Our search yielded 20 documents and webpages.

In addition to online searches, we contacted state regulatory officials, identified through their state's DEP website, in states with facilities emitting EtO above the 100 per million risk threshold. We contacted each state's Director of Air Quality to request documents not available online, including actions that state DEPs have taken regarding facilities that emit EtO since the NATA release in 2018, the nature and extent of their interaction with communities around the facility, and whether the state DEP is collaborating with their regional EPA office or local or state government officials to achieve a reduction in risk. All contacts with state officials were conducted over e-mail or phone in September 2020 (Supplementary Table S1).

We performed a content analysis of the identified documents and webpages. Qualitative content analysis was used, allowing for a systematic and retrospective review of existing data.²⁹ Using the methodology in the study by Attride-Stirling, 2001, actions and reactions were categorized into the following impact themes: (1) community outcry, (2) EPA involvement, (3) DEP involvement, (4) legislative action, and (5) industry action.³⁰

EPA, state DEP, and industry documents and websites were assessed for impact actions. For community webpages and documents, content analysis focused on potential reactions. Community reactions were characterized as present or not present. Recognizing that the internet information may not fully encompass the entirety of a community's response, we elected not to quantify or grade the value or degree of response. Introduced and adopted bills were characterized as legislative action.

²⁹Ibid. Szwiec *et al.* (2020).

³⁰J. Attride-Stirling. "Thematic Networks: An Analytic Tool for Qualitative Research." *Qualitative Research* 1 (2001): 385–405.

RESULTS

According to the NATA, 654 facilities emit EtO in the United States.³¹ Thirty-one facilities are associated with an estimated cancer risk of over 100 per million in neighboring census tracts. These 31 facilities, including 11 commercial sterilizers and 20 chemical plants, are located in 13 states and Puerto Rico, representing 7 EPA regions (Table 1). Over half of these facilities are located in EPA Region 6, which includes facilities in New Mexico, Texas, and Louisiana.

The demographic information for communities within one mile of the facility is outlined in Supplementary Table S2. The average percent population living below the poverty line was 18%.³² This is higher than the national average of 14.6% population living below the poverty line.³³ Twenty-three facilities (74%) are located in EJ communities.

Actions and reactions at these facilities were identified and categorized into impact themes (Table 2). Table 3 reports the impact themes by facility.

Community reaction

Analysis of documents showed that seven facilities, all commercial sterilizers, had strong pushback from the community. In Willowbrook, IL, community members formed a local organization, *Stop Sterigenics*. They held protests, contacted local politicians, and spread news through their website to the community.³⁴ *Stop Sterigenics* then expanded to Georgia, where another Sterigenics site is located in a suburb of Atlanta.³⁵ Community response then followed at the other sterilizers in Illinois and Georgia, Medline and Becton Dickinson, respectively.

Similarly, in Pennsylvania, community members created a Facebook group titled "Lower B Braun ethylene oxide emissions" where they shared information about B Braun and their EtO emissions.³⁶ Community action was a good predictor of EPA and DEP response. Documents showed that EPA and DEP were involved in every community with significant community action. In communities without community action, the EPA and DEP were not involved.

State DEP and regional EPA reaction

Community actions were often followed by involvement at either the federal or state level. State DEPs in Colorado, Illinois, Georgia, and Michigan performed air monitoring

³¹Ibid. World Health Organization (2020).

³²U.S. Census Bureau. American Community Survey, 2013–2017 American Community Survey 3-Year Estimates. Tables A14006, A13003, B04001.

³³Ibid. Pellow (2000).

³⁴Citizens for Clean Air. *Stop Sterigenics*. (2020). <<https://www.stopsterigenics.com/>>. (Last accessed on December 10, 2020).

³⁵Ibid. Bowen (2009).

³⁶B. Lower. *BRAUN Ethylene Oxide Emissions*. (2019). <https://www.facebook.com/pg/Lower-B-BRAUN-ethylene-oxide-emissions-105265381009813/about/?ref=page_internal>. (Last accessed on December 15, 2020).

TABLE 1. FACILITIES THAT EMIT ETHYLENE OXIDE, LEADING TO ESTIMATED CANCER LEVELS OF OVER 100 PER MILLION, IN THE ENVIRONMENTAL PROTECTION AGENCY 2014 NATIONAL AIR TOXICS ASSESSMENT RELEASED IN 2018

Facility	EPA region	Location	Type of facility	Emissions (tons)	Total emissions (state)	Total emissions (EPA region)
BASF Corporation	2	Warren, NJ	Chemical plant	0.5	0.5	1.2
Edwards Lifesciences Corporation	2	Anasco, PR	Commercial sterilizer	0.7	0.7	
Croda Inc	3	New Castle, DE	Chemical plant	1.3	1.3	8.32
Union Carbide Corporation	3	Kanawha, WV	Chemical plant	2.9	3.72	
Union Carbide Corporation	3	South Charleston, WV	Chemical plant	0.82		
B Braun Medical Inc	3	Allentown, PA	Commercial sterilizer	3.3	3.3	
Becton Dickinson	4	Covington, GA	Commercial sterilizer	3.0	4.6	
Sterigenics	4	Smyrna, GA	Commercial sterilizer	1.6		
Solvay	4	Charleston, SC	Chemical plant	1.0		
Sterigenics	5	Willowbrook, IL	Commercial sterilizer	2.8	4.3	4.9
Medline Industries Inc	5	Waukegan, IL	Commercial sterilizer	1.5		
Viant	5	Grand Rapids, MI	Commercial sterilizer	0.6	0.6	
Sterigenics	6	Santa Teresa, NM	Commercial sterilizer	2.9	2.9	
Union Carbide Corporation	6	Institute, LA	Chemical plant	15.0	40.2	90.7
BASF Corporation	6	Geismar, LA	Chemical plant	7.1		
Sasol Chemicals LLC	6	Westlake, LA	Chemical plant	6.3		
Shell Chemical LP	6	Geismar, LA	Chemical plant	4.8		
BCP Ingredients Inc	6	New Hampton, LA	Chemical plant	2.5		
The Dow Chemical Company	6	Plaquemine, LA	Chemical plant	1.8		
Evonik Materials Corp	6	Reserve, LA	Chemical plant	1.6		
Taminco US LLC	6	St. Gabriel, LA	Chemical plant	1.1		
Midwest Sterilization Corp	6	Laredo, TX	Commercial sterilizer	7.9	43.9	
Port Neches Plant	6	Port Neches, TX	Chemical plant	10.8		
Texas Operations	6	Longview, TX	Chemical plant	7.4		
Clear Lake Plant	6	Pasadena, TX	Chemical plant	5.9		
Dow, Inc	6	Seadrift, TX	Chemical plant	5.2		
Bayport Underwood Plant	6	Pasadena, TX	Chemical plant	4.0		
Conroe Facility	6	Conroe, TX	Chemical plant	2.7		
Midwest Sterilization Corp-Jackson	7	Jackson, MO	Commercial sterilizer	3.5	6.2	6.2
BCP Ingredients Verona Plant	7	Verona, MO	Chemical plant	1.8		
Terumo BCT Sterilization Services Inc	8	Lakewood, CO	Commercial sterilizer	1.1	1.1	1.1

EPA, Environmental Protection Agency.

around their respective EtO-emitting facilities.^{37,38,39,40} Risk assessments were produced for Terumo Blood and

Cell Technologies (BCT) in Colorado and Sterigenics in Illinois, and the state agencies publicized results of the air monitoring and risk assessment of EtO in the community.^{41,42}

In states where sterilizers have not closed or significantly cut emissions, federal and state involvement was minimal. The EPA, despite its offer in 2018 to assist states with EtO monitoring and assessment, had no apparent involvement in Region 2, 6, or 7, representing 18 of the 31 EtO-emitting industries of concern. In Penn-

³⁷Colorado Department of Public Health and Environment. *Community Risk Assessment of Ethylene Oxide Near Terumo BCT in Lakewood, Colorado*. (Toxicology and Risk Assessment Program, 2018).

³⁸U.S. Environmental Protection Agency. *Risk Assessment Report for the Sterigenics Facility in Willowbrook, Illinois*. (National Center for Environmental Assessment Office of Research and Development U.S. Environmental Protection Agency, 2019).

³⁹Georgia Department of Environmental Resources. *Quality Assurance Project Plan for the Georgia Ambient Air Monitoring Program Ethylene Oxide*. (Air Protection Branch Ambient Air Monitoring Program, 2019).

⁴⁰Michigan Department of Environment, Great Lakes, and Energy. *Frequently Asked Questions: Ethylene Oxide Air Emissions, Viant Medical Inc.* (Air Quality Division, 2019).

⁴¹Ibid. Pennsylvania Department of Environmental Protection (2020).

⁴²Ibid. Attride-Stirling (2001).

TABLE 2. IDENTIFICATION AND CATEGORIZATION OF CONTENT IN DOCUMENTS AND WEBPAGES THAT MET INCLUSION CRITERIA

<i>Impact themes</i>	<i>Content</i>	<i>Data sources</i>
Community outcry	Online discussions through social media; formation of local organizations; organized community protests; and civil action lawsuits	Stop Sterigenics, Citizens for Clean Air (2020) Lower B. BRAUN ethylene oxide emissions, Facebook (2019) Public Troubled by inaction at EPA meeting in Verona, Monett Times (2019) EPA raises concern about elevated cancer risk for people living around B. Braun plant near Allentown, The Morning Call (2019) Students Against Ethylene Oxide. (2019)
EPA involvement	Hosting meetings for communities; releasing statements about the facility; and conducting further research (air monitoring and risk assessment)	Ethylene oxide: Technical Reviews and Outreach to Potentially Affected Communities, U.S. Environmental Protection Agency (2020) Risk Assessment Report for the Sterigenics Facility in Willowbrook, Illinois, U.S. Environmental Protection Agency (2019) Agency Actions on Ethylene Oxide. U.S. Environmental Protection Agency (2020) Ethylene Oxide Emissions from the Smyrna, Georgia Sterigenics Facility. U.S. Environmental Protection Agency (2020) Covington, Georgia Becton Dickinson Facility. U.S. Environmental Protection Agency (2020) Report: Management Alert - Prompt Action Needed to Inform Residents Living Near Ethylene Oxide-Emitting Facilities About Health Concerns and Actions to Address Those Concerns. U.S. Environmental Protection Agency: Office of Inspector General (2020)
DEP involvement	Hosting meetings for communities; releasing statements about the facility; and conducting further research (air monitoring and risk assessment)	Ethylene Oxide (C ₂ H ₄ O). Illinois Environmental Protection Agency (2020) Ethylene Oxide Carcinogenic Dose-Response Assessment, Texas Commission on Environmental Quality (2019) State Only Operating Permit No. 39-00055, B BRAUN MED INC, Pennsylvania Department of Environmental Protection (2020) Quality Assurance Project Plan for the Georgia Ambient Air Monitoring Program Ethylene Oxide, Georgia Department of Environmental Resources (DNR) Press Release: EGLE signs Consent Order with Viant Medical to end its use of ethylene oxide, Michigan Department of Environment, Great Lakes, and Energy (EGLE) (2019) Frequently Asked Questions: Ethylene Oxide Air Emissions, Viant Medical Inc, Michigan Department of Environment, Great Lakes, and Energy (EGLE) (2019) Community risk assessment of ethylene oxide near Terumo BCT in Lakewood, Colorado, Colorado Department of Public Health and Environment (2018)
Industry actions	Installation of new technology to control emissions; decreased use of EtO; and discontinuation of all EtO use or production	Press Release: EGLE signs Consent Order with Viant Medical to end its use of ethylene oxide, Michigan Department of Environment, Great Lakes, and Energy (EGLE) (2019) Community risk assessment of ethylene oxide near Terumo BCT in Lakewood, Colorado, Colorado Department of Public Health and Environment (2018) State Only Operating Permit No. 39-00055, B BRAUN MED INC, Pennsylvania Department of Environmental Protection (2020)
Legislative actions	Adopted legislation related to EtO	Public Act 101-0022, S. 1852, 2019 Illinois General Assembly House Bill 927, 2019 Illinois General Assembly

DEP, Department of Environmental Protection; EtO, ethylene oxide.

TABLE 3. IMPACT THEMES BY FACILITY: COMMUNITY, INDUSTRY, STATE, AND FEDERAL ACTIONS SINCE THE NATIONAL AIR TOXICS ASSESSMENT WAS RELEASED IN 2018

Facility	EPA region	Community outcry	EPA involved	State DEP involved	Risk assessment	State legislation passed	Industry closed/cut emissions	EJ community
BASF Corporation (NJ)	2							
Edwards Lifesciences Corporation (PR)	2							X
Croda Inc. (DE)	3							X
Union Carbide Corporation (WV)	3							
Union Carbide Corporation (WV)	3							X
B Braun Medical Inc. (PA)	3	X	X	X			X	
Becton Dickinson (GA)	4	X	X	X		X	X	X
Sterigenics (GA)	4	X	X	X		X	X	X
Solvay (SC)	4		X	X				X
Sterigenics (IL)	5	X	X	X	X	X	X	
Medline Industries Inc. (IL)	5	X	X	X		X	X	X
Viant (MI)	5	X	X	X			X	X
Sterigenics (NM)	6							X
Union Carbide Corporation (LA)	6							X
BASF Corporation (LA)	6							X
Sasol Chemicals LLC (LA)	6							
Shell Chemical LP (LA)	6							X
BCP Ingredients Inc. (LA)	6							X
The Dow Chemical Company (LA)	6							X
Evonik Materials Corp (LA)	6							X
Taminco US LLC (LA)	6							X
Midwest Sterilization Corp (TX)	6			X ^a				X
Port Neches Plant (TX)	6			X ^a				X
Texas Operations (TX)	6			X ^a				X
Clear Lake Plant (TX)	6			X ^a				X
Dow Inc. (TX)	6			X ^a				X
Bayport Underwood Plant (TX)	6			X ^a				X
Conroe Facility (TX)	6			X ^a				X
Midwest Sterilization Corp-Jackson (MO)	7	X	X	X				
BCP Ingredients Verona Plant (MO)	7	X	X	X				
Terumo BCT Sterilization Services Inc. (CO)	8		X	X	X		X	

^aAction in Texas by the Texas Commission on Environmental Quality was to weaken EtO emission requirements. EJ, environmental justice.

sylvania, the regional EPA office acknowledged the risks of EtO in Lehigh County and publicly stated that it would work with the Pennsylvania DEP to look into these risks.⁴³ However, to date, neither additional air monitoring nor a risk assessment has been released.

B Braun, the commercial sterilizer in Lehigh County, has received a new permit from the DEP, in which the company submitted a plan to reduce emissions by 99% by installing new controls.⁴⁴ With the exception of one public meeting held by the EPA in Missouri, there has been no identifiable action by federal or state agencies at

⁴³Binghui Huang. *EPA Raises Concern About Elevated Cancer Risk for People Living Around B. Braun Plant Near Allentown*. (The Morning Call, 2019). <<https://www.mcall.com/>>. (Last accessed on December 8, 2020).

⁴⁴Pennsylvania Department of Environmental Protection. *State Only Operating Permit No. 39-00055, B BRAUN MED INC.* (Air Quality Program, 2020). <http://files.dep.state.pa.us/Air/AirQuality/AQPortalFiles/Permits/PermitDocuments/1295883%5b39-00055%5d_Issued_v1.pdf>. (Last accessed on December 2, 2020).

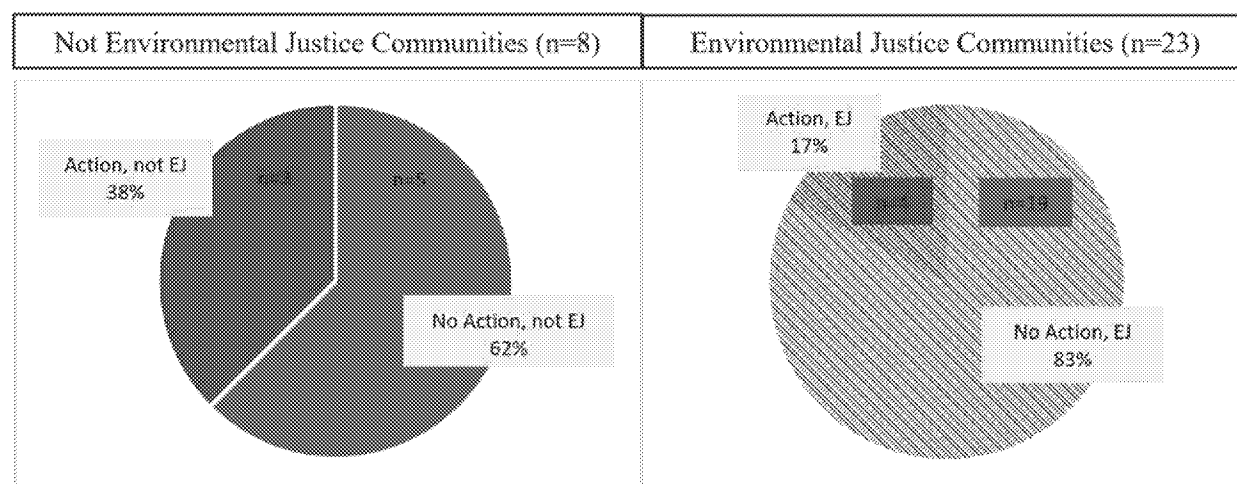


FIG. 1. Proportion of action and no action in communities located within a one-mile radius of each identified facility, categorized by their EJ status. EJ, environmental justice.

any of the facilities in Missouri, New Mexico, or Puerto Rico.⁴⁵

We identified perceived limitations on actions that state departments could take, including prioritization of other environmental issues in that state and existing federal statutes that require change before state departments can take action. One state department noted that the state was waiting for the EPA to update the federal regulation before acting.

In contrast to all other state agencies, after the release of the NATA, the Texas Commission on Environmental Quality (TCEQ) stated that they believed the cancer level set by the EPA for EtO was too stringent.⁴⁶ A representative from the TCEQ stated that the TCEQ believes that there were errors in EPA's model of determining carcinogenicity. As a result, the TCEQ released their own assessment of EtO carcinogenicity that decreased the cancer risk value of EtO, therefore allowing for weaker emission constraints for the facilities that emit EtO in Texas.⁴⁷ Texas remains the state with the highest cumulative EtO emissions at 43.9 tons per year.

Legislative action

In response to pressure from community members and state agencies, legislation limiting EtO emissions was passed in two states, Illinois and Georgia, impacting two

sterilizers in each state.^{48,49} To comply with the legislation, facilities had to either cut emissions by 99% or close.

Industry action

Three sterilizers voluntarily closed down or cut emissions: Terumo BCT in Colorado, Viant Medical in Michigan, and B Braun in Pennsylvania. After results of air monitoring became public, Terumo BCT installed new emission controls; Viant Medical announced that it was going to stop all sterilization using EtO; and B Braun voluntarily cut emissions by 99% in July 2020 through installation of new technology.^{50,51,52}

Impacts on EJ communities

Twenty-three of the 31 EtO-emitting facilities (74%) that lead to elevated cancer risks are located in EJ communities (Fig. 1). Of these 23 facilities, only 4 (17%) have closed or cut emissions since the 2018 release of NATA. In comparison, 37% of facilities located in non-EJ communities have closed or cut emissions (Fig. 1).

⁴⁵Murray Bishoff. *Public Troubled by Inaction at EPA Meeting in Verona*. (Monett Times, 2019). <www.monett-times.com>. (Last accessed on December 5, 2020).

⁴⁶Texas Commission on Environmental Quality. *Ethylene Oxide Carcinogenic Dose-Response Assessment*. (Toxicology, Risks Assessment, and Research Division, 2019).

⁴⁷Ibid. Georgia Department of Environmental Resources (2019).

⁴⁸Public Act 101-0022, S. 1852, 2019 General Assembly (Illinois 2019).

⁴⁹House Bill 927, 2019 General Assembly, 2017 Reg. Sess. (Georgia 2019).

⁵⁰Ibid. Pennsylvania Department of Environmental Protection (2020).

⁵¹EGLE Media Office. *Press Release: EGLE Signs Consent Order with Viant Medical to End Its Use of Ethylene Oxide*. (EGLE Media Office, 2019). <https://www.michigan.gov/egle/0,9429,7-135-3308_3323-513575--,00.html>. (Last accessed on December 2, 2020).

⁵²U.S. Environmental Protection Agency. *Ethylene Oxide: Technical Reviews and Outreach to Potentially Affected Communities*. (U.S. Environmental Protection Agency, 2020). <https://www.epa.gov/sites/production/files/2021-01/documents/status_report_braun_medical.allentown_pa.pdf>. (Last accessed on December 5, 2020).

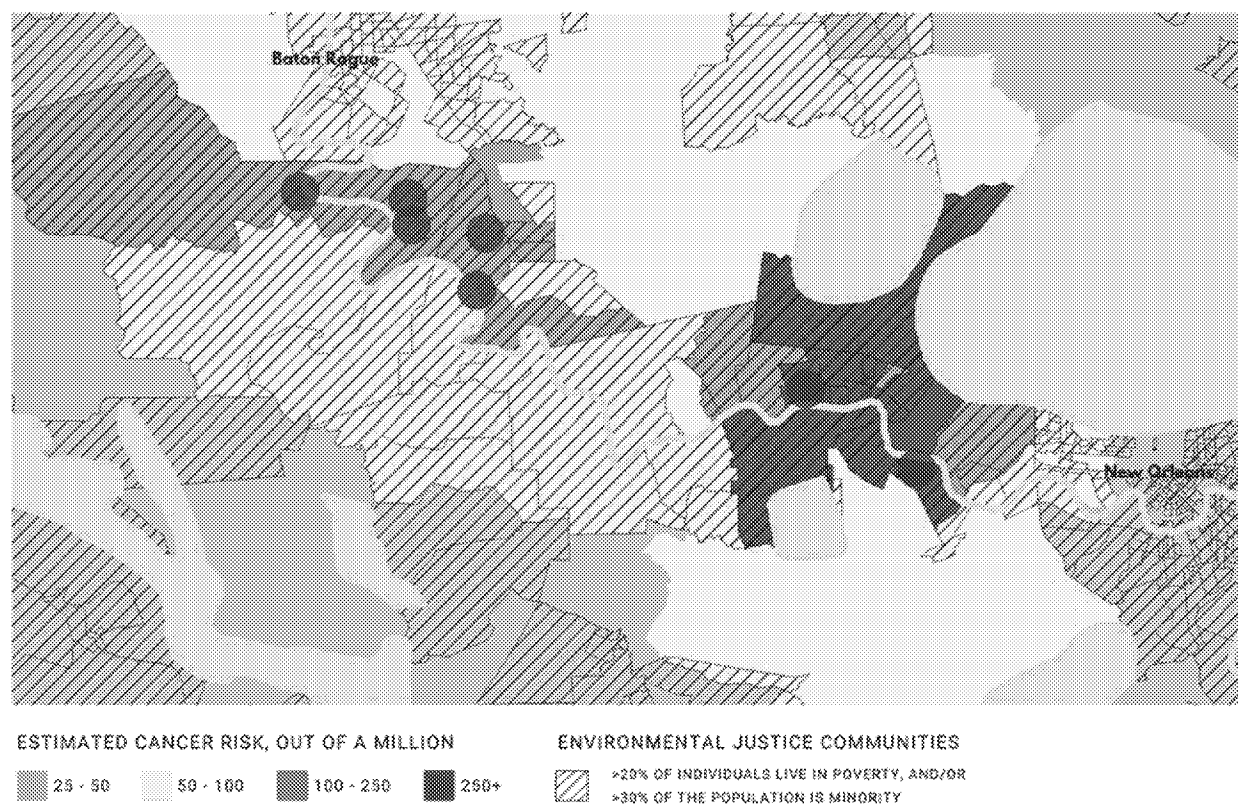


FIG. 2. Seven chemical plants between Baton Rouge and New Orleans, all located in EJ communities, and the resultant estimated cancer risks due to ethylene oxide emissions.

Facilities that have closed or cut EtO emissions were located in higher-income whiter communities with poverty levels of 15%, compared with 19% in areas where no change has occurred (Supplementary Fig. S1).⁵³ The highest income communities, located around Sterigenics in Illinois and Georgia, were the communities that had the strongest involvement at all levels, resulting in their local facilities' closure before restrictions from state legislation went into effect.

In addition, areas that saw emission reductions were on average less diverse with an average 60% white non-Latine population, compared with 39% in areas where no change has occurred.⁵⁴ Three of the commercial sterilizers that saw no action were located in communities where over 80% of the population was Latine⁵⁵ (Supplementary Fig. S2).

Overall, there was more federal and state involvement in higher-income white communities than in EJ communities. Despite 7 of the 8 facilities in Louisiana being located in EJ communities, we found no evidence of any involvement from the EPA or the state. Figure 2 shows the clustering of 7 chemical plants emitting EtO in the region between Baton Rouge and New Orleans. This

region, colloquially known as "Cancer Alley," has predominantly EJ communities (Fig. 2).

In contrast, in Illinois, where federal and state agencies have been actively involved with EtO emissions since the release of the NATA, Figure 3 shows that the communities residing in the area with cancer risks from Sterigenics in Willowbrook, IL, are not EJ communities.

DISCUSSION

This study, using the lens of the EIF theory, examines multiple stakeholder involvement in establishment and maintenance of environmental injustice. The interaction among stakeholders has been inferred through the content analysis of websites and documents and interviews of state agency personnel. Through this analysis, we have elucidated an inadequate regulatory system for protection of human health from hazardous air pollutants by using the specific example of EtO.

The mission of the EPA is to protect human health and the environment. According to its website, the agency accomplishes its mission through enforcement of federal laws "administered and enforced, fairly."⁵⁶ This case

⁵³Ibid. Pellow (2000).

⁵⁴Ibid.

⁵⁵Ibid.

⁵⁶U.S. Environmental Protection Agency. *Our Mission and What We Do*. (U.S. Environmental Protection Agency, 2020). <<https://www.epa.gov/aboutepa/our-mission-and-what-we-do>>. (Last accessed on August 5, 2021).

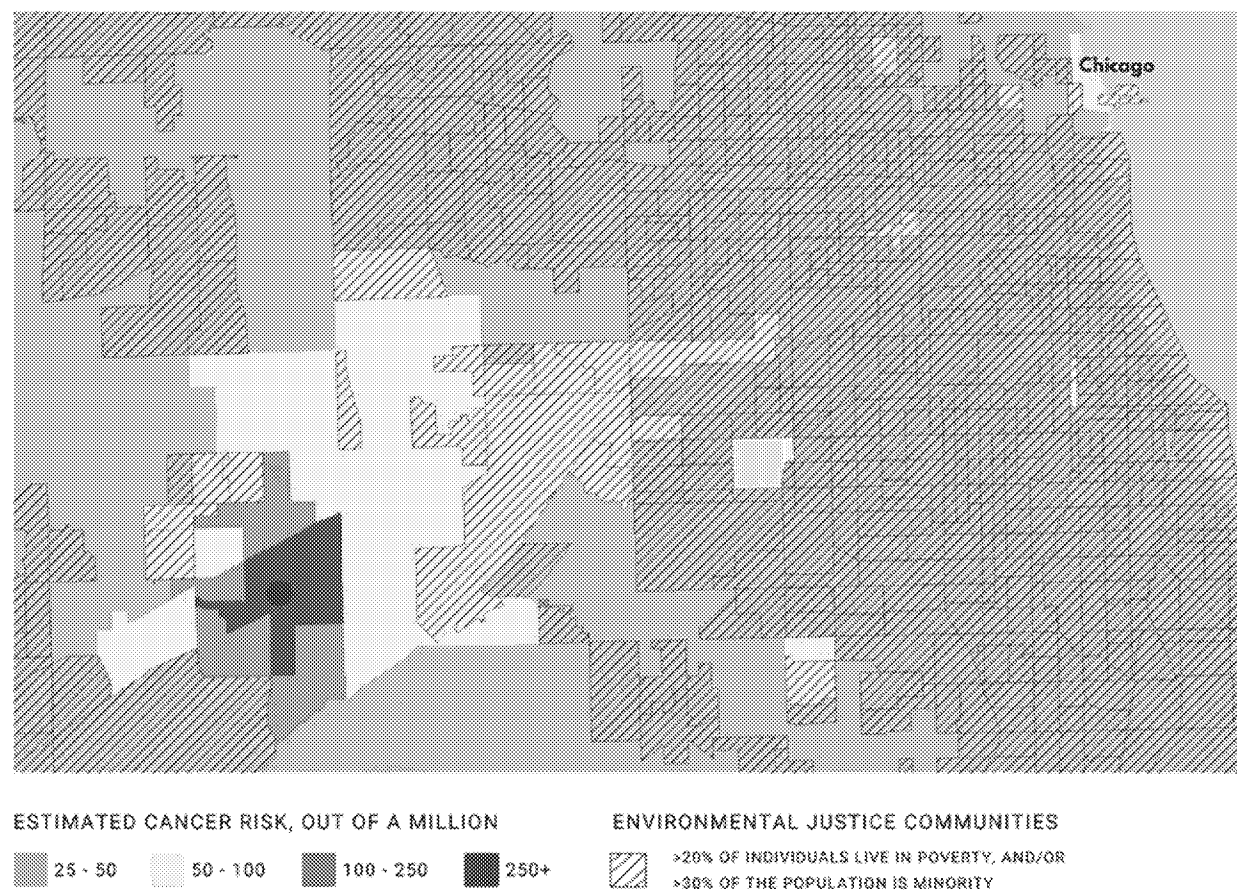


FIG. 3. Sterigenics in Willowbrook, IL, located outside of EJ communities, and the resultant estimated cancer risks due to ethylene oxide emissions.

study of EtO, a known human carcinogen, illustrates flaws in the regulatory process established by the EPA to accomplish its mission.

With regard to the determination of which chemicals it deems worthy of human carcinogen status, the EPA is in conflict with the World Health Organization's IARC. This is not the first time that EPA and IARC have reached different conclusions on carcinogenicity. In one case, analysis of the difference found that while IARC prioritized peer-reviewed studies, EPA relied mostly on registrant-commissioned, unpublished regulatory studies.⁵⁷

It is not within the scope of the current analysis to fully explore the reasons why it took EPA 22 additional years after IARC to come to the conclusion that EtO was a known human carcinogen. However, in those 22 years and the 5 years since then, there has been no federal regulation that has protected the public. Even if we consider only the last 5 years, why has there not been federal regulation on a chemical that was classified as a known human carcinogen by the EPA?

⁵⁷C.M. Benbrook. "How Did the US EPA and IARC Reach Diametrically Opposed Conclusions on the Genotoxicity of Glyphosate-Based Herbicides?." *Environmental Sciences Europe* 31 (2019): 2.

This delay continues to put 31 communities across the country at ongoing unacceptable risk of cancer. In addition, some communities bear more of the risk. Figure 2 shows how elevated cancer risks are disproportionately located in EJ communities due to the clustering of facilities, all emitting EtO. EPA's inaction is neither protective of human health nor is it fairly applied.

Cancer Alley is home to many more industrial facilities than those shown on this map, which emit other hazardous air pollutants that contribute cumulatively to air pollution and cancer risk in this region.⁵⁸ Currently, federal law does not require a quantitative analysis of cumulative risks in the risk assessment performed in the application of federal regulation despite this approach being recommended by the National Research Council in its solicited analysis of the EPA Risk Assessment Process in 2010.⁵⁹ In addition to the inadequacy of the current

⁵⁸U.S. Environmental Protection Agency. *National Emissions Inventory*. (U.S. Environmental Protection Agency, 2020). <https://edap.epa.gov/public/extensions/nei_report_2014/dashboard.html#point-db>. (Last accessed on August 7, 2021).

⁵⁹E. Abt, J.V. Rodricks, J.I. Levy, L. Zeise, and T.A. Burke. "Science and Decisions: Advancing Risk Assessment." *Risk Anal* 30 (2010): 1028–1036.

risk assessment approach, equity in environmental exposure is part of the EPA mission statement, but not part of its auditable mandate.

The Environmental Justice Executive Order 12898 of 1994 applies to federal agencies, but suffers from the same limitation of all executive orders, a lack of accountability.⁶⁰ It aspires to promote EJ without any metrics of achievement. It does not apply to private industry and has not been used to inform permitting standards in any meaningful way. This case study underscores the ineffectiveness of the Executive Order on Environmental Justice to protect vulnerable communities, but offers insight into the opportunity to do so through updated federal regulation.

States often fill gaps in federal regulation with state legislation, but only two state legislatures, Illinois and Georgia, passed legislation to protect their residents. Recognizing that the EPA has delegated authority for enforcement of federal regulation to the states, it is reasonable to assume that state DEPs would take action on established increased cancer risk. In the case of EtO, 13 states and 1 territory were informed by the EPA of significantly increased risk of cancer for their residents.

Of the 11 states whose legislatures did not take action, only 4 state DEPs, Pennsylvania, Michigan, Missouri, and Colorado, became involved in addressing this issue and one state, Texas, actually took steps to weaken restrictions on EtO. In five states and one territory, we found no evidence that residents were informed or engaged around EtO. In fact, several DEPs specifically mentioned that they were waiting for the EPA to take action and felt constrained to do so on their own.

This case study suggests that states cannot be relied upon to protect their residents even when informed about the risk by the federal EPA.

Exerting community pressure on legislators and regulators was quite effective, in that identified community action led to a decrease in EtO emissions, except in Missouri. Although it is beyond the scope of this analysis to fully explore the strategies and extent of community action, it seems reasonable to assume that a critical amount of action would be required to achieve positive results. Although community advocacy has been an important catalyst of change in American democracy, it should not be relied upon to protect the larger population from significant health hazards.

A fundamental lack of equity can be seen in the placement of EtO-emitting facilities and the manner in which their carcinogenic emissions are addressed or ignored. The current legislative and regulatory frameworks are ill-equipped to address health impactful hazards and even less well equipped to do so when residents are also exposed to numerous other health-impacting emission sources. Health disparities are expected to grow in this setting of structural racism.

The solution requires a change in the framework of assessing and addressing hazardous pollutants, which incorporates cumulative impact analysis, timeliness of action, and equity in application.

Limitations

The analysis presented here has several limitations. Knowledge of community involvement was limited to online sources. It is likely that individual community members may have contacted legislators and regulators with their concerns. Some community groups may not have an online presence and may conduct activities through texting, distribution of flyers, or personal contact. Our study methods would not have identified these community-organizing strategies.

Identification of federal and state plans for future regulation was limited by the knowledge and willingness of the individuals with whom we spoke to disclose this information and the agency's disclosures online. No legislators were contacted, so legislative efforts that were not yet filed have not been included.

Our analysis of community, federal, and state actions concluded in 2020. Updates at facilities and in communities that occurred after 2020 are not reflected in this project. This analysis also does not include the effects of the COVID-19 pandemic on the operation of facilities, specifically the commercial sterilizers that are used to sterilize medical equipment.

CONCLUSIONS

This project highlights the inadequacy and inconsistency of the current regulatory framework in the United States to protect the public from significant health risks due to industrial emissions. It also describes significant inequity in discretionary actions taken by the EPA, state DEPs, and state legislatures to assess and mitigate these risks. In nearly every case of reduced hazardous emissions, community involvement was critical in achieving action.

State legislative action can be effective, but rarely occurred, and should not be relied upon to mitigate significant health impacts. By evaluating the behavior of key stakeholders involved in protection of human health from hazardous air pollution using EIF theory, we elucidated inadequacies in the current regulatory process. EJ communities continue to experience disproportionate exposure to known human carcinogens due to clustering of facilities in their communities, while regulators lack the regulatory tools to assess and mitigate cumulative exposure through permitting and other strategies.

Results from this project can be used to advocate for and by EJ communities across the United States. This work supports the need to improve the regulatory framework in place for state and federal agencies to cumulatively assess environmental pollutants and incorporate these assessments into permitting processes to better protect the public. An improved regulatory process

⁶⁰Exec. Order No. 12898, 59 Fed. Reg. 32 (February 16, 1994).

incorporated into the CAA would embrace core EJ principles and use quantitative analytics to assess community vulnerability and cumulative exposure in permitting and enforcement.

This approach would reinforce the effectiveness of federal oversight, particularly in states and regions with a history of poor health protection for residents.

AUTHOR DISCLOSURE STATEMENT

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SUPPLEMENTARY MATERIAL

Supplementary Figure S1
Supplementary Figure S2
Supplementary Table S1
Supplementary Table S2

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